

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA,

Plaintiff,

– against –

RAHSAN A. HAKIM and ADONIAH A.
RAHSAN, *d/b/a* SUNDIAL HERBAL
PRODUCTS,

Defendants.

OPINION AND ORDER

18 Civ. 5726 (ER)

Ramos, D.J.:

The United States (the “Government”) brings this action to enjoin defendants Rahsan A. Hakim (“Hakim”) and Adoniah A. Rahsan (“Rahsan,” and with Hakim “Defendants”), from violations of the Federal Food, Drug and Cosmetic Act (the “FDCA”), 21 U.S.C. § 301 et seq. Specifically, the Government seeks to enjoin Defendants from distributing unapproved new and misbranded drugs in violation of 21 U.S.C. § 331(a) and (d), and from misbranding drugs held for sale in violation of 21 U.S.C. § 331(k). Before the Court are cross-motions for summary judgment pursuant to Federal Rule of Civil Procedure 56. For the reasons set forth below, the Government’s motion for summary judgment is GRANTED and Defendants’ motion for summary judgment is DENIED.

I. BACKGROUND

A. Factual Background¹

Hakim and Rahsan are a father and son who do business as Sundial Herbal Products (“Sundial”), an unincorporated entity that Defendants have identified as a partnership, located at 3609 Boston Road, Bronx, New York. Gov’t Stmt., ¶ 1. Defendants prepare, pack, and hold numerous products they describe as tonics, “herbs and roots,” and herbal tea. *Id.* ¶ 4. Hakim has formulated proprietary blends for the tonics manufactured by Sundial, and is responsible for manufacturing operations and major financial decisions. *Id.* Rahsan oversees Sundial with his father, and is responsible for quality control and sales. *Id.* Defendants also own a physical retail store that shares a building with Sundial, called the Koromantee Health Food Store. *Id.* ¶ 10. Koromantee sells Defendants’ products to other retail stores and to online buyers. *Id.* ¶ 11. Approximately thirty percent of Koromantee’s sales are to out-of-state customers. *Id.* Defendants promote their products on their Facebook page, the radio, and their website, www.sundialherbs.com, where customers can also purchase their products. *Id.* ¶¶ 12, 13.

Between October 4 and November 15, 2012, the Food and Drug Administration (the “FDA”) conducted an inspection of Sundial’s facility (the “2012 Inspection”). *Id.* ¶ 14. During the 2012 Inspection, an FDA investigator documented that Defendants were making claims that their products are intended for use in diagnosing, curing, mitigating, treating, and/or preventing a wide variety of diseases such as syphilis, asthma, diabetes, cancer, HIV/AIDS, and high blood pressure. *Id.* ¶ 15. The FDA investigator also collected Defendants’ product labels that made

¹ The following facts are drawn from the Government’s Rule 56.1 Statement (“Gov’t Stmt.”) Doc. 26, Defendants’ response to the Government’s Rule 56.1 Statement (“Defs.’ Resp.”), Doc. 36, Defendants’ Rule 56.1 Statement (“Defs.’ Stmt.”) Doc. 37 Ex. A, the Government’s response to Defendants’ Rule 56.1 Statement (“Gov’t Resp.”), Doc. 43, the Government’s reply to Defendants’ response to the Government’s Rule 56.1 Statement (“Gov’t Reply”), Doc. 44, and the parties’ supporting submissions. They are undisputed except where otherwise noted. Additionally, any citation to the parties’ Rule 56.1 Statements incorporates by reference the documents cited therein.

those claims. *Id.* ¶ 16. At the conclusion of that inspection, the investigator issued an FDA Form 483, a report of objectionable conditions that the investigator observed, to Defendants. *See* Decl. of Ronald M. Pace (“Pace Decl.”), Doc. 30, Ex. 3 at 7–20. Subsequently, the FDA issued a warning letter² on March 24, 2013 (the “Warning Letter”), notifying Defendants that they were marketing unapproved new and misbranded drugs.³ Gov’t Stmt., ¶¶ 17, 18. The 2013 Warning Letter provided, among other things, an extensive list of Defendants’ labels making disease claims⁴. *See* Pace Decl., Ex. 2 at 1–2. They include, for instance, claims that a product named Woman Back Tonic “helps to break up abnormal growths, cysts & fibroids,” and that another product named Wood and Root Tonic helps with asthma and flu. *Id.* Additionally, the Warning Letter identified six of Defendants’ products whose very names make disease claims, including “Arthritis,” “Asthma,” “Diabetics,” “Flu-Allergy Hayfever,” “Hepatitis/Liver,” and “Worm & Parasites.” *Id.* On June 28, 2013, Sundial sent the FDA a letter in response to the 2013 Warning Letter.⁵ *See* Decl. of Rahsan A. Hakim (“Hakim Decl.”), Doc. 48, Ex. 1 at 2.

² According to the FDA’s website, a Warning Letter is issued by the FDA as a notification to a manufacturer that it has significantly violated FDA regulations. Food and Drug Administration, *About Warning and Close-Out Letters* (April 29, 2019), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/about-warning-and-close-out-letters>. The letter identifies the violation, makes clear that the company must correct the violation, and provides directions and a timeframe for the violator to inform the FDA of its plans for correction, which the FDA subsequently checks for adequacy. *Id.*

³ The Warning Letter also identified deficiencies in how Defendants prepared, packed, labeled, or held their products that made them adulterated and misbranded dietary supplements under the FDCA. Those deficiencies include: (1) failure to sample the ingredients or subject them to testing or examination to confirm their identity prior to using them; (2) failure to establish finished product specifications for the identity, purity, strength, and composition of the products; (3) failure to keep written master manufacturing records for the products; (4) failure to maintain proper batch records with information such as the identity and weight or measure of each component used; (5) failure to make and keep written quality control procedures; (6) failure to make and keep written procedures for the review and investigation of product complaints; (7) failure to maintain equipment or utensils to protect components and dietary supplements from being contaminated; (8) failure to include nutrition labeling on a product’s label; (9) failure to declare all of the ingredients on a product’s label; and (10) failure to identify the products using the term dietary supplement on their labels. *Id.*

⁴ According to the FDA, a statement that a certain product is intended for use in diagnosing, curing, mitigating, treating, and/or preventing a wide variety of diseases is a “disease claim.” *See* Decl. of Milan S. McGorty (“McGorty Decl.”), Doc. 29, ¶ 15; *see also* 21 C.F.R. 101.93(g).

⁵ In the letter, Hakim generally represented to the FDA that he had made some adjustments regarding product complaints, equipment maintenance, batch records, declaration of products’ ingredients, and that he would update

Between January 7 and February 12, 2014, the FDA conducted a second inspection of Defendants' facility (the "2014 Inspection"). Gov't Stmt., ¶ 19. During that inspection, an FDA investigator observed that Defendants were continuing to make similar claims on their products' labels. *Id.* ¶ 20. At the end of the 2014 Inspection, the investigator issued another FDA Form 483 to Defendants, noting that Defendants had not corrected the deficiencies previously identified. Pace Decl., Ex. 1 at 9. In response, Sundial sent a letter to the FDA on April 1, 2014, explaining its procedure for handling product complaints and detailing the ingredients of some of its products. *See* Hakim Decl., ¶¶ 7, 8. According to Defendants, on April 17, 2014, the FDA responded and confirmed receipt of Sundial's April 1 letter.⁶ *Id.* ¶ 8. One year later, on May 13, 2015, Sundial sent another letter to the FDA stating that it has incorporated some of the FDA's prior recommendations regarding "detailed batch record, product complaints log, disclaimer on the herbal combinations, [equipment] maintenance log." *Id.* ¶ 10.

Between February 7 and 17, 2017, the FDA conducted a third inspection of Defendants' facility (the "2017 Inspection"), during which an FDA investigator interviewed Rahsan and Hakim regarding their operations.⁷ Gov't Stmt., ¶ 21. Rahsan accompanied the FDA investigator during the inspection, answered questions about the company's operations, and identified and provided copies of requested records. *Id.* ¶ 23. Meanwhile, Hakim answered questions relating to Sundial's manufacturing operations. *Id.* ¶ 22. The FDA investigator collected records including, but not limited to, product labels and documentation of components

his products' labels. *Id.* The letter otherwise contained no mention of the issue of disease claims in Defendants' products' labeling. *Id.*

⁶ The record does not contain the FDA's response.

⁷ The record contains no evidence of communications between the FDA and Defendants from May 14, 2015 to February 6, 2017.

and finished products traveling in interstate commerce.⁸ *Id.* ¶¶ 25–28. At the close of the inspection, the FDA investigator informed Rahsan that certain of Defendants’ product labels contained disease claims.⁹ *Id.* ¶ 29. Furthermore, the investigator reminded Rahsan that the FDA brought this issue to Defendants’ attention during both the 2012 and 2014 inspections, as well as in the 2013 Warning Letter.¹⁰ *Id.* Rahsan acknowledged that he understood the problem of having disease claims on product labels and on Defendants’ website, but he did not commit to correcting either the labels or website. *Id.* ¶ 31.

On March 10, 2017, FDA personnel reviewed Defendants’ website, and determined that it still continued to make disease claims about their products. Gov’t Stmt., ¶ 32. On November 15, 2017, Defendants received a letter from Joon H. Kim, the Acting United States Attorney for the Southern District of New York, advising that the Government was prepared to file a civil action and seek a permanent injunction against them, unless Defendants agreed to the entry of a consent decree¹¹ on the proposed terms.¹² Hakim Decl., Ex. 1 at 28–29. On January 18, 2018, Defendants responded and rejected the proposed consent decree. *Id.* Ex. 1 at 30–36. Further review of Defendants’ website, one year later, on March 9 and June 25, 2018 revealed that

⁸ Specifically, the FDA documented that Defendants shipped several finished products, including Wood and Root Tonic, to North Carolina on February 13, 2017. *Id.* ¶ 27. The FDA further documented that Defendants received shipments of components from Jamaica that they used in manufacturing their products. *See* McGorty Decl., ¶ 11.

⁹ The Government compiled a comprehensive list of seventy-four products, along with their labels stating that these products are intended for use in diagnosing, curing, mitigating, treating, and/or preventing a wide variety of diseases, including but not limited to HIV/AIDS, cancer, Ebola, and Alzheimer’s disease. *See* Decl. of Mariton Dos Santos (“Santos Decl.”), Doc. 27, Appendix 1.

¹⁰ Defendants’ response that the FDA Form 483, reports issued at the conclusion of the 2012 and 2014 inspections, do not identify any labeling violations regarding disease claims, is immaterial. Indeed, Defendants’ response does not controvert the fact that an FDA investigator brought the issue to Defendants’ attention *during* the 2012 and 2014 inspections. Moreover, Defendants’ response does not controvert the undisputed fact that their labeling issue was specifically identified in the 2013 Warning Letter.

¹¹ The record does not contain the proposed consent decree.

¹² The letter stated that the FDA had advised the DOJ of Defendants’ violations of the FDCA. *Id.*

Defendants' website continued to contain similar disease claims. Gov't Stmt., ¶¶ 33, 34. On June 25, 2018, the Government commenced the instant action.

On June 27, 2018, two days after commencement of the instant action, Defendants, after consulting with "competent FDA counsel," requested that Sundial's webmaster¹³ remove all active links to Sundial's website." Defs' Stmt. ¶ 7. As of June 28, 2018, customers have been unable to purchase Sundial's products online.¹⁴ *Id.* ¶ 8. Instead, customers would be redirected to a page that reads "We'll be back SOON." *Id.* ¶ 11. Furthermore, Rahsan testified that as of June 2018, all physical product labels have been removed. *See* Decl. of Rahsan ("Rahsan Decl."), Doc. 39, ¶ 2.

The Government filed the instant motion on January 9, 2020. Doc. 24. On February 27 and 28, 2020, almost eight years after the 2012 Inspection and more than 32 months after this action was filed, an FDA investigator purchased and photographed, at Defendants' retail store, four of the seventy-four products that the FDA had previously identified as containing disease claims.¹⁵ *See* Decl. of Devon O. Seymour ("Seymour Decl."), ¶ 4, Ex. 1. Three of the four products had physical product labels making disease claims, contrary to what Rahsan had previously represented. *Id.* A review of Defendants' website on February 28 and March 2, 2020 showed that the website continued to contain the same violative claims previously found. *See* Supp. Decl. of Lillian C. Aveta ("Aveta Decl."), ¶ 3, Ex. 2. The Government detailed these findings in its reply memorandum of law filed on March 20, 2020 in further support of its motion

¹³ According to Sundial's webmaster Sylvester Powell, he is responsible for managing and maintaining Sundial's website. *See* Decl. of Sylvester Powell, Doc. 38, ¶ 2.

¹⁴ The Government, for purposes of the instant motion, does not dispute that customers have been unable to purchase Sundial products from its website since June 28, 2018. Gov't Resp. ¶ 8.

¹⁵ A review of Defendants' website on February 28 and March 2, 2020, showed that it provides directions on how to get to their retail store. *See* Aveta Decl., ¶ 3, Ex. 1.

for summary judgment and in opposition to Defendants’ cross-motion. *See* Doc. 41. On that day, the Government also produced photographs of the four products purchased and screenshots of Defendants’ website containing disease claims as attachment to two declarations from the FDA investigators that made those findings. *See* Docs. 40, 41, 42.

Upon receipt of the Government’s filings on March 20, 2020, Defendants purportedly conducted an investigation into their retail store. *See* Hakim Decl., ¶ 19. Defendants assert that those three products were “inadvertently overlooked” and contained old product labels, all of which have been removed as of March 20, 2020. *Id.* ¶¶ 19, 21. Defendants also instructed that Sundial’s webmaster remove the pages with disease claims from their website. *Id.* ¶ 22.

Lastly, it is undisputed that the FDA’s records contain no approvals for, or even submissions by Defendants for any new drug application (“NDA”), abbreviated new drug applications (“ANDA”), or investigational new drug (“IND”) exemption applications, for any of Defendants’ products. Gov’t Stmt. ¶ 39. The FDA has also conducted comprehensive searches of publicly available medical and scientific literature for Defendants’ products and was unable to identify any published adequate and well-controlled studies demonstrating that any of Defendants’ products are generally recognized as safe and effective in connection with their intended uses. *Id.* ¶ 38.

B. Procedural Background

On June 25, 2018, the Government commenced the instant action to enjoin Defendants from selling drugs and dietary supplements¹⁶ that they claim will treat syphilis, asthma, diabetes, cancer, AIDS, high blood pressure and other diseases. *See* Doc. 1, ¶ 1. On September 25, 2018,

¹⁶ While the Government initially sought to enjoin Defendants from distributing adulterated and misbranded dietary supplements, it has represented in the instant motion that it no longer seeks that injunctive relief. *See* Mem. of Law in Supp. re Mot. for Summ. J. (“Gov’s SJ Mem.”) at 1 n.1.

Defendants filed their answer. Doc. 9. On January 9, 2020, the Government moved for summary judgment. Doc. 24. The Government also filed a proposed order entering a permanent injunction. Doc. 31. On February 20, 2020, Defendants responded and cross-moved for summary judgment. Docs, 35, 37. On April 3, 2020, Defendants also filed a competing proposed order for a permanent injunction. Doc. 49. On April 6, 2020, the Court directed the parties to report if they wished to jointly propose a consent injunction, or indicate that they intend on standing on their previous submissions. *See* Doc. 50. Both the Government and Defendants advised the Court that they wish to stand on their previous submissions. *See* Docs. 51, 52, 53.

C. The Government's Proposed Injunction¹⁷

In summary, the Government's proposed injunction prohibits Defendants from manufacturing, preparing, processing, packing, labeling, holding, and distributing any drug unless and until either: (1) an NDA, ANDA, or IND is in effect for their drugs [not included in Defendants' proposed injunction]; or (2) they meet various requirements demonstrating compliance with the FDCA. It also includes various oversight and remedial measures as well as authorizes the FDA to take actions to verify and ensure compliance.

Specifically, the requirements demonstrating compliance with the FDCA include:

- That Defendants remove from product labels, promotional material, websites, and social media pages all disease claims.
- That Defendants retain, at their own cost, a qualified, trained, and experienced drug labeling expert to review and report to the FDA on Defendants compliance with the issued injunction and FDCA.
- That Defendants, at their own cost, recall and destroy, under the FDA's supervision, all drugs manufactured, packed, labeled, held, and distributed from

¹⁷ Defendants' proposed injunction largely borrows the language of the Government's proposed order, while leaving out several provisions to be noted.

2014 through the date the injunction is issued. [Not included in Defendants' proposed injunction].

- That FDA representatives inspect Defendants' facility to determine its compliance with the FDCA, and notifies Defendants in writing of their compliance, costs of which are to be reimbursed by Defendants.

Next, the oversight and remedial measures include:

- Within fifteen days of the issuance of the injunction, Defendants shall provide the FDA with a proposed plan to destroy all unapproved new and misbranded drugs in Defendants' possession. Defendants shall complete the destruction under the FDA's supervision upon receiving authorization, costs of which shall be borne by Defendants. [Not included in Defendants' proposed injunction].
- Upon resuming operations, Defendants shall retain an independent person, who may be the same person as the drug labeling expert mentioned above, to conduct semiannual audit inspections of their facility and prepare an audit report in accordance with the requirements specified in the proposed injunction. [Not included in Defendants' proposed injunction].
- If the audit report indicates any noncompliance with the injunction or FDCA, they shall be corrected by Defendants within fifteen days of receipt of the report, unless otherwise notified by the FDA. [Not included in Defendants' proposed injunction].

The proposed injunction authorizes the FDA to:

- In the event of noncompliance, to notify Defendants in writing and order Defendants to, among other things, cease manufacturing, preparing, processing, packing, labeling, holding and distributing any or all drugs, recall at their own costs any drugs found in violation, to revise aforementioned reports or destruction plan, and take any other corrective actions as deemed necessary by the FDA to bring Defendants into compliance. [Not included in Defendants' proposed injunction].
- Have immediate access to Defendants' facility and to conduct necessary inspections without prior notice.
- Request a hard or digital copy of Defendants' labels, promotional materials, websites, or social media pages. [Not included in Defendants' proposed injunction].

Other items include:

- Defendants are also required to publicize the injunction to be issued, by posting a copy in a common area at their facility and any other business location, and serving it on their officers and employees. [Not included in Defendants' proposed injunction].
- Defendants are further required to notify the FDA, within fifteen days, of any changes to the ownership, name, or character of Sundial. [Not included in Defendants' proposed injunction].
- Should Defendants fail to comply with any provision of the injunction or the FDCA, Defendants shall pay to the Government, following the expiration of fifteen days' written notice to the FDA, a thousand dollars a day and additional liquidated damages twice the retail value of any drugs distributed in violation.
- Should the Government bring and prevail a contempt action to enforce the terms of the order, Defendants shall reimburse the Government all fees and costs incurred.

II. LEGAL STANDARD

Summary judgment is appropriate where “the movant shows that there is no genuine dispute as to any material fact.” Fed. R. Civ. P. 56(a). “An issue of fact is ‘genuine’ if the evidence is such that a reasonable jury could return a verdict for the non-moving party.” *Senno v. Elmsford Union Free Sch. Dist.*, 812 F. Supp. 2d 454, 467 (S.D.N.Y. 2011) (citing *Scr Joint Venture L.P. v. Warshawsky*, 559 F.3d 133, 137 (2d Cir. 2009)). A fact is “material” if it might affect the outcome of the litigation under the governing law. *Id.* The party moving for summary judgment is first responsible for demonstrating the absence of any genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the moving party meets its burden, “the nonmoving party must come forward with admissible evidence sufficient to raise a genuine issue of fact for trial in order to avoid summary judgment.” *Saenger v. Montefiore Med. Ctr.*, 706 F. Supp. 2d 494, 504 (S.D.N.Y. 2010) (internal quotation marks omitted) (citing *Jaramillo v. Weyerhaeuser Co.*, 536 F.3d 140, 145 (2d Cir. 2008)).

In deciding a motion for summary judgment, the Court must “construe the facts in the

light most favorable to the non-moving party and must resolve all ambiguities and draw all reasonable inferences against the movant.” *Brod v. Omya, Inc.*, 653 F.3d 156, 164 (2d Cir. 2011) (quoting *Williams v. R.H. Donnelley, Corp.*, 368 F.3d 123, 126 (2d Cir. 2004)). However, in opposing a motion for summary judgment, the non-moving party may not rely on unsupported assertions, conjecture or surmise. *Goenaga v. March of dimes birth defects found.*, 51 F.3d 14, 18 (2d Cir. 1995). To defeat a motion for summary judgment, “the non-moving party must set forth significant, probative evidence on which a reasonable fact-finder could decide in its favor.” *Senno*, 812 F.Supp. 2d at 467–68 (citing *Anderson v. Liberty lobby*, 477 U.S. 242, 256–57 (1986)).

“When confronted with cross-motions for summary judgment, the Court analyzes each motion separately, ‘in each case construing the evidence in the light most favorable to the non-moving party.’” *Peterson v. Kolodin*, No. 13 Civ. 793 (JSR), 2013 WL 5226114, at *1 (S.D.N.Y. Sept. 10, 2013) (quoting *Novella v. Westchester Cty.*, 661 F.3d 128, 139 (2d Cir. 2011)); *see also Morales v. Quintel Entm’t, Inc.*, 249 F.3d 115, 121 (2d Cir. 2001) (“[e]ach party’s motion must be examined on its own merits, and in each case all reasonable inferences must be drawn against the party whose motion is under consideration.”) (Citation omitted). The Court is not required to resolve the case on summary judgment merely because all parties move for summary judgment. *Morales*, 249 F.3d at 121.

III. DISCUSSION

The Government contends that the undisputed evidence in this case establishes that: (1) Defendants have introduced unapproved new drugs into interstate commerce in violation of 21 U.S.C. § 331(d); (2) Defendants have caused those drugs to be misbranded while they are held for sale after shipment of one or more of their components in interstate commerce, in violation of

21 U.S.C. § 331(k); and (3) Defendants have introduced such misbranded drugs into interstate commerce, in violation of § 331(a). Specifically, the Government contends that Defendants' products are "drugs" because Defendants' website and their physical products labels make disease claims. In response, Defendants do not dispute that their product labels made disease claims or that they otherwise violated the FDCA¹⁸, but contend any such labeling, or online or offline sale of their products have ceased since June 28, 2018. As a result, Defendants aver that summary judgment must be granted in their favor based on the Government's failure to prove that their products are drugs under the FDCA. Furthermore, Defendants contend that its cessation of sale and unlawful labeling of its products removes the need for any injunctive relief. The Court disagrees.

A. Defendants' Products are Drugs Under the FDCA

The FDCA broadly defines "drug" as including any product "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals." 21 U.S.C. § 321(g)(1)(B). Whether a product is a "drug" under the FDCA depends upon its intended use. *See id.*; *see also United States v. Undetermined Quantities of an Article of Drug Labeled as "Exachol"*, 716 F. Supp. 787, 791 (S.D.N.Y. 1989). The key factor in whether a product may be regulated as a drug is the "vendor's intent in the sale of the product to the public." *National Nutritional Foods Ass'n. v. Mathews*, 557 F.2d 325, 333 (2d Cir. 1977) (internal citations omitted). It is well established that the FDA is not bound by the vendor's subjective claims of intent, and that the intended use of a product may be deduced or ascertained from "labeling,

¹⁸ In their papers, Defendants make reference to three inspections that were made of their facility by the New York State Department of Agriculture and Markets on March 6, 2014, May 27, 2015, December 16, 2016, respectively. Each inspection resulted in a finding that Defendants were in "substantial compliance" with the New York State Agriculture and Markets Law. *See* Hakim Decl., Ex. 1 at 24, 26, 27. Those findings are irrelevant to the instant action, particularly in light of Defendants' acknowledgement of their violations of the FDCA.

promotional materials, advertising, and ‘any other relevant source.’” *Id.* at 334 (internal citations omitted); *see also* 21 C.F.R. § 201.128.

The FDCA defines “label” as, among other things, “a display of written, printed, or graphic matter upon the immediate container of any article,” 21 U.S.C. § 321(k), and “labeling” as “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article,” 21 U.S.C. § 321(m). Labeling includes written materials that are physically attached to the article, but is “not restricted to labels that are on or in the [transported] article.” *Kordel v. United States*, 335 U.S. 345, 349-50 (1948); *see also United States v. Guardian Chem. Corp.*, 410 F.2d 157, 160-61 (2d Cir. 1969). Courts have found that a product’s website that “supplements and explains” the product constitutes labeling within the meaning of the FDCA. *Kordel*, 335 U.S. at 350; *see also Sandoval v. PharmaCare US, Inc.*, 730 F. App’x 417 (9th Cir. 2018); *United States v. Berst*, No. 11 Civ. 6370 (TC), 2012 WL 4361408, at *4 (D. Or. Aug. 2, 2012) (citing *United States v. Lane Labs USA Inc.*, 427 F.3d 219, 223 (3d Cir. 2005)), report and recommendation adopted, 2012 WL 4361559 (D. Or. Sept. 20, 2012).

Classification of a product—even if derived from natural ingredients—as a food does not preclude its classification as a drug under the FDCA. *National Nutritional Foods*, 557 F.2d 325 at 334. Indeed, regardless of the physical effect of a product, it will be considered and regulated as a drug under the FDCA once its labeling and promotional claims suggest intended uses bringing it within the relevant definition of a drug. *See U.S. v. Article of Drug ... “Sudden Change”*, 409 F.2d 734, 739 (2d Cir. 1969); *see also* 21 C.F.R. § 201.128.

Here, the record establishes that Defendants’ products are drugs under the FDCA. The labels that the FDA collected during the 2012, 2014, and 2017 inspections and reviews of

Defendants' website, indisputably establish that Defendants claimed that their products were intended for use in diagnosing, curing, mitigating, treating, and/or preventing a wide variety of diseases. In fact, Defendants admitted as much before the instant action was filed. *See* Defs' Resp., ¶ 15 (admitting that "[d]uring the 2012 Inspection, Defendants were making claims that their products are intended for use in diagnosing, curing, mitigating, treating and/or preventing a wide variety of diseases"); *Id.* ¶ 16 (admitting that the FDA investigator collected Defendants' product labels that claimed to be used for diagnosing, curing, mitigating, treating, and/or preventing a wide variety of diseases); *Id.* ¶ 20 (admitting that "[d]uring the 2014 Inspection, and FDA investigator documented that Defendants were continuing to make claims that their products are intended for use in diagnosing, curing, mitigating, treating and/or preventing a wide variety of diseases") and; *Id.* ¶ 24 (admitting that "[s]everal of Defendants' product labels collected during the 2017 Inspection stated that such products were intended for use in diagnosing, curing, mitigating, treating, and/or preventing a wide variety of diseases").

Now, however, Defendants argue that if there is no labeling, a product cannot be a drug under the FDCA. Therefore, Defendants aver that the Government cannot prove that their products are drugs because they have ceased any marketing or labeling of their products since June 28, 2018, three days after this action was filed. This argument has no merit as a matter of law or fact. In the first place, the lack of labeling of a product does not preclude a finding that it is a drug under the FDCA based on its intended use, which may be determined from "any other relevant source." *See Sudden Change*, 409 F.2d at 739 (collecting cases); *see also United States v. Travia*, 180 F. Supp. 2d 115, 119 (D.D.C. 2001) (rejecting the argument that nitrous oxide cannot be a drug, even if balloons in which nitrous oxide was sold contained no labeling or advertising).

Moreover, and contrary to Defendants' assertion, the record shows that they did not cease marketing or labeling of their products on June 28, 2018. Indeed, Sundial's website continued to include disease claims for Defendants' products well past June 28, 2018. The website also provided directions to Defendants' retail store. Thus, a customer can read Defendants' claims that their products cure or prevent diseases from their website, and visit their retail store to purchase such products, as FDA investigators did in February 2020. In any event, courts regularly use previous labelling as evidence of a drug's intended use even when there is a later disclaimer or revised labeling. *See Drug labeled as "Exachol"*, 716 F.Supp. at 791. Indeed, by Defendants' logic, any manufacturer may avoid liability for past violations of the FDCA by stopping their challenged activities in response to litigation, which simply cannot be the case. *See City of Mesquite v. Aladdin's Castle, Inc.*, 455 U.S. 283, 289 (1982) ("It is well settled a defendant's voluntary cessation of a challenged practice does not deprive a federal court of its power to determine the legality of the practice").

Accordingly, because a product is a drug under the FDCA if it is labeled and marketed as such, 21 U.S.C. § 321 (g)(1)(B), Defendants' products are drugs.

B. Violations of the FDCA

Defendants Distributed Unapproved New Drugs

The FDCA prohibits the introduction of unapproved new drugs into interstate commerce. 21 U.S.C. § 331(d). A new drug may not be introduced or delivered for introduction, or caused to be introduced or delivered for introduction, into interstate commerce unless the FDA has approved an NDA or an ANDA, or the drug qualifies for an exemption as an IND. 21 U.S.C. § 335(b), (i), (j).

A drug is a “new drug” under the FDCA if it “is not generally recognized, among experts ... as safe and effective for use under the condition prescribed, recommended, or suggested in the labeling thereof” and it has been used to a material extent or for a material time under such conditions. 21 U.S.C. § 321 (p)(1). For a drug to be considered “generally recognized as safe and effective,” there must be substantial evidence of its effectiveness and safety for its intended uses. 21 U.S.C. § 355(d); *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 629 (1973) (“the hurdle of ‘general recognition’ of effectiveness requires at least ‘substantial evidence’ of effectiveness for approval of an NDA”).

The exemption of “generally recognized” drug products from the definition of a “new drug” under the FDCA is a “very narrow one.” *Premo Pharm. Labs., Inc. v. United States*, 629 F.2d 795, 802 (2d Cir. 1980). The FDA has issued regulations defining “adequate and well-controlled studies,” 21 C.F.R. § 314.126, which “elaborates” on the substantial evidence test. *Weiberger*, 412 U.S. at 649. The Second Circuit Court of Appeals has instructed that the key is that only pre-existing drug products found through “careful study by scientific experts to have been generally recognized on the basis of usage and documentation to be safe and effective” alone qualify for the exemption. *Premo*, 629 F.2d at 802–03. General unawareness of the product by experts preclude application of the exemption. *Id.* In addition, there must be a consensus by qualified experts that the drug product is safe and effective for its labeled indications. *Id.* Lastly, that consensus should generally be based on not only “clinical experience,” but also “publication in the scientific literature.” *Id.*

Here, it is undisputed that the FDA has conducted comprehensive searches of publicly available medical and scientific literature for Defendants’ products and was unable to identify any published adequate and well-controlled studies demonstrating that any of Defendants’ drugs

are generally recognized as safe and effective for their intended uses. Given the complete lack of such studies, there can be no consensus among qualified experts under the substantial evidence test of the FDCA. Accordingly, Defendants' drugs are not generally recognized as safe and effective, and are new drugs.

In addition, the record shows, and Defendants admit, that they do not have any NDA, ANDA, and IND submissions in the FDA's records, or any approvals for such submissions with respect to their products. As such, Defendants' drugs are unapproved new drugs.

Lastly, the record establishes that Defendants have introduced their drugs into interstate commerce. Record evidence establishes that thirty percent of their sales were to out-of-state customers. Defs.' Resp., ¶ 11; *Id.* ¶ 27. In addition, the FDA documented during the 2017 Inspection, that Defendants shipped several finished products to North Carolina. For all the foregoing reasons, Defendants have violated 21 U.S.C. § 331(d), by introducing or causing the introduction into interstate commerce of unapproved new drugs.

Defendants Drugs are Misbranded

The FDCA also prohibits misbranding of a drug while such article is held for sale after shipment in interstate commerce. 21 U.S.C. § 331 (k). As relevant to this case, a drug is misbranded if its labeling fails to bear "adequate directions for use" and is not exempt from this requirement. The FDA has defined "adequate directions for use" as "directions under which the layman can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5.

The FDCA defines a prescription drug as "[a] drug intended for use by man which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. § 353 (b)(1)(A). By definition,

a prescription drug is “not safe for use except under the supervision of a practitioner licensed by law to administer such drug.” *See* 21 U.S.C. § 353(b)(1)(A); *see also United States v. Regenerative Scis., L.L.C.*, 741 F.3d 1314, 1324 (D.C. Cir. 2014). Courts have observed that prescriptions drugs are presumptively misbranded, because a prescription drug’s label alone cannot provide adequate instructions under which the layman can use it safely for its intended purposes. *Id* (collecting cases). A prescription drug can avoid being mislabeled only by qualifying for either a regulatory exemption issued by the FDA, 21 C.F.R. § 201.100, or the statutory exemption under 21 U.S.C. § 353(b)(2). The statutory exemption applies when licensed practitioners distribute drugs to patients via prescriptions. *See* 21 U.S.C. § 353(b)(2).

Here, the record shows that many of Defendants’ drugs are intended for treating serious diseases or conditions such as HIV, cancer, and Ebola, all of which require diagnosis and management by a physician. *See Santos Decl.*, ¶ 36; *see also id.*, Appendix 1. As such, they are *only* safe for use under the supervision of a physician, which brings them within the definition of prescription drugs. As discussed above, they are presumptively misbranded unless they qualify for either a regulatory or the statutory exemption, none of which apply here. *See United States v. Articles of Drug ... Rucker*, 625 F.2d 665, 675 (5th Cir. 1980); *see also United States v. Premo Pharm. Labs., Inc.*, 511 F. Supp. 958, 977 n.23 (D.N.J. 1981) (“A drug is misbranded if it is a prescription drug that is an unapproved new drug, because a prescription drug cannot bear adequate directions for use required by such statute...and the lack of an approved NDA means that there is no exemption from the adequate directions of use requirement.”) (citations omitted).

Defendants’ drugs are also misbranded because they lack adequate instructions for lay use. To begin with, Defendants do not dispute that their products’ labels did not bear adequate directions for use before the instant action was filed. *See Defs.’ Resp.*, ¶ 37 (claiming that

Defendants are no longer distributing all physical product labels and stopped online labeling on June 28, 2018, but not disputing the Government's allegation that Defendants' products are misbranded prescription drugs...do not bear adequate directions for use"). Furthermore, Courts have held that there can be no adequate instruction for lay use without clinical evidence showing the "safety and efficacy of the drugs." *United States v. Undetermined Quantities of Articles of Drug*, 145 F.Supp.2d 692, 701-02 (D. Md. 2001). As previously discussed, the FDA is not aware of any clinical trials or studies establishing that Defendants' drugs are generally recognized as safe and effective, which would make it possible to write adequate directions for their use by lay people.

Accordingly, because their drugs are misbranded, Defendants have violated 21 U.S.C. § 331(a) by introducing them into interstate commerce. In addition, Defendants have violated 21 U.S.C. § 331(k) by causing the shipment of one or more of their components in interstate commerce, given that they receive components from Jamaica. *See* McGorty Decl., ¶ 11; *see also* Defs.' Resp., ¶ 25 (Defendant admitting that they received components used in the manufacture of their products from Jamaica).

C. The Need for Injunctive Relief

Having found that the Government is entitled to summary judgment that Defendants distributed unapproved new and misbranded drugs, as well as misbranded drugs in violation of the FDCA, the Court turns to the Government's requested relief of a permanent injunction.

The FDCA's overarching goal is to "protect the public health." *See United States v. Article of Drug...Bacto-Unidisk*, 394 U.S. 784, 798 (1969). Injunctive relief "has been routinely awarded" under the FDCA, *United States v. Syntrax Innovations, Inc.*, 149 F. Supp. 2d 880, 884 (E.D. Mo. 2001), and is appropriate when the government has demonstrated that defendants have

violated the applicable statute and that there is some reasonable likelihood that the violations may recur. *See United States v. Diapulse Corp. of Amer.*, 457 F.2d 25, 28-29 (2d Cir. 1972). Courts have found that even a single violation may suffice as basis for the government to seek injunctive relief. *See United States v. N.Y.C. Fish, Inc.*, 10 F. Supp. 3d 355, 369 (E.D.N.Y. 2014). Given the FDCA’s explicit authorization of injunctive relief to restrain violations thereof, 21 U.S.C. § 332(a), the Second Circuit has held that the Government need not show specific injury to the public because “the statute is, in a sense, an implied finding that the violations will harm the public.” *Diapulse Corp.*, 457 F.2d at 28.

Here, Defendants’ sole argument is that that their voluntary corrective measures removes the need for such injunctive relief. It is clear, however, that a court’s power to grant injunctive relief survives discontinuance of the illegal conduct. *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953). In deciding whether injunctive relief is appropriate after a defendant claims to have voluntarily ceased illegal behavior, it is key that there be some “cognizable danger of recurrent violation.” *Id.* A court may base its decisions on “all the circumstances,” including the following factors: (1) the bona fides of the expressed intent to comply; (2) the effectiveness of the discontinuance; and (3) in some cases, the character of the past violations. *Id.*; *see also EEOC v. KarenKim, Inc.*, 698 F.3d 92, 100 (2d Cir. 2012) (applying factors “in determining whether to impose an injunction where a defendant has ceased the offending conduct”). Defendants’ past record of noncompliance is an important indicator of the likelihood of recurrent violation. *Diapulse Corp.*, 457 F.2d at 29. Courts should be particularly cautious when faced with corrective measures that appear to take place in anticipation of or in reaction to legal action. *See United States v. Oregon State Medical Society*, 343 U.S. 326, 333 (1952). In order to show a case is moot such that injunctive relief is not necessary, Defendants must bear the “heavy”

burden to establish that “there is no reasonable likelihood that the wrong will be repeated.” *W.T. Grant Co.*, 345 U.S. at 623; *see also Iron Arrow Soc’y v. Heckler*, 464 U.S. 67, 72 (1983) (“Defendants face a heavy burden to establish mootness in such cases because otherwise they would simply be free to return to old ways after the threat of a lawsuit has passed.” (quotation omitted)).

Applying the above-mentioned principles, the cognizable danger of future violations is clear in the present case, and a permanent injunction is thus appropriate. Here, Defendants only took partial corrective measures in response to the threat of litigation. Furthermore, Defendants’ history of repeated violations and failure to make corrections despite multiple warnings from the FDA indicates a complete lack of “bona fides of the expressed intent to comply” with the law. *W.T. Grant Co.*, 345 U.S. at 633. Indeed, even as recently as two months ago, FDA investigators observed on Defendants’ website that they continue to make claims that their products are intended for use in treating or preventing diseases. Defendants’ past violations are also egregious, as they made claims that their products could cure cancer, HIV, and Ebola, among other serious diseases. Lastly, absent injunctive relief, nothing prevents Defendants from returning to their old ways. *See Federal Trade Commission v. Cuban Exch., Inc.*, No. 12 Civ. 5890, 2014 WL 3756358, at *4 (discussing how defendants’ website was only taken down in response to court’s issuance of a temporary restraining order and preliminary injunction, and absent permanent relief, there was “nothing to stop defendants from obtaining new websites and continuing their scheme”). Indeed, given the number of past warnings to Defendants over a period of eight years, they cannot satisfy the burden to establish that there is no reasonable likelihood that the wrong will be repeated. Accordingly, injunctive relief is warranted on the facts of this case.

D. Entry of Permanent Injunction

The FDCA provides the FDA with “broad authority” in safeguarding public health and safety from “products not proven to be safe and effective for their alleged uses.” *See United States v. Blue Ribbon Smoked Fish, Inc.*, 56 F. App’x. 542, 543 (2d Cir. 2003). An injunction under the FDCA may “sweep broadly” as needed to prevent violations that appear likely to recur. *Diapulse Corp.*, 457 F.2d at 29. Given the well-established principle that one “can have no vested interest in a business activity found to be illegal,” the party against whom an injunction is granted under the FDCA may not object on the basis that it would “put him out of the business.” *Id.* (internal citations omitted). Defendants’ expressed intention not to continue violative conduct does not eliminate the need for an injunction. *See Twentieth Century Fox Film Corp. v. Marvel Enters.*, 155 F. Supp. 2d 1, 48-49 (S.D.N.Y. 2001) (finding that even if violative conduct had ceased, that “an award of preliminary relief is not moot” as “defendants have not provided the Court with a consent injunction or other enforceable assurance that their alleged infringement will not be repeated”). Nevertheless, the Court also bears in mind that injunctive relief should be “narrowly tailored to fit specific legal violations,” and should not inflict “unnecessary burdens on lawful activity.” *Blue Ribbon Smoked Fish, Inc.*, 56 F. App’x. at 543 (internal citation omitted).

The Court is satisfied that the Government’s proposed injunction is indeed tailored to Defendants’ violations of the FDCA as determined above. Indeed, orders containing nearly identical terms have been routinely entered by courts. *See e.g., United States v. N.Y.C. Fish, Inc.*, No. 13 Civ. 2909 (RRM), 2014 WL 1343246 (E.D.N.Y. Apr. 3, 2014); *United States v. Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d 30, 50 (E.D.N.Y. 2001), *aff’d in part and vacated in part*, 56 F. App’x 542, 542-44 (2d Cir. 2003).

As noted above, Defendants raised, for the first time in their reply brief, the possibility that they would agree to an entry of a consent injunction, in the form that they proposed. However, the parties have represented that they have not been able to come to an agreement, and that they intend on standing on their previous submissions. In any event, after a close comparison of the parties' competing proposed injunctions, the Court finds that the egregiousness of Defendants' history of violative conduct weighs heavily in favor of adoption of the Government's proposal. Accordingly, the Court will issue an order entering the Government's proposed injunction.

IV. CONCLUSION

For the foregoing reasons, the Government's motion for summary judgment and injunctive relief is GRANTED, and Defendants' motion for summary judgment is DENIED. The Clerk of the Court is respectfully directed to terminate the motions, Docs 24 and 37. It is SO ORDERED.

Dated: May 26, 2020
New York, New York

A handwritten signature in blue ink, appearing to read 'Edgardo Ramos', is written over a horizontal line.

Edgardo Ramos, U.S.D.J.